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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/527,646	NITSCH ET AL.	
	Examiner	Art Unit	
	Iqbal H. Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,21 and 30-33* is/are pending in the application.

4a) Of the above claim(s) *30-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

In response to a previous Office action, a non-final requirement (mailed on 3/24/2006), Applicants filed a response and amendment received on June 26, 2006. Claims 1-2 and 21 are amended and new claims 30-33 are added. Claims 3-20 and 22-29 are cancelled. Claims 1-2 and 21 and now newly added claims 30-33 are pending in the instant Office action and will be examined herein.

Amended claims 1-2 and 21 and the newly submitted claims 30-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The amended claims (claims 1-2 and 21) and the newly added claims (claims 30-33) comprise three distinct inventions: #1) An isolated protein comprising the amino acid sequence selected from the group consisting of SEQ ID NOs: 1 to 12 or a neuronally active fragment thereof, having one N-terminal, C-terminal and/or internal deletion and a pharmaceutical composition for the treatment of neuronal injuries or diseases (claims 1-2 and 21); #2) A method of diagnosing a disease or disease state (a neuronal disease, a tumor disease or fertility) using the protein of claim 1 as a diagnostic marker comprising the step of detecting the presence, absence or amount of the protein of claim 1 by RT PCR and Northern blot immunological methods (claims 30-31); and #3) A method of diagnosing a disease or disease state (a neuronal disease, a tumor disease or fertility) using the nucleic acid encoding the protein of claim 1 as a diagnostic marker comprising the step of detecting the presence, absence or amount of the protein of claim 1 by RT PCR and Northern blot immunological methods (claims 32-33). Presently, the claims comprise three patentably distinct inventions such as one is product (#1) and two patentably

distinct methods (#2 and #3). It is to be mentioned here that the two methods previously grouped as Group VIII and Group IX in Restriction Requirement Office Action. Amended claims 1-2 and 21 and newly added claims 30-31 and 32-33 represent two new methods that is patentably distinct, which is different from the claimed invention originally presented and examined i.e. an isolated protein of SEQ ID NO: 1 and a composition. The methods drawn to diagnosis of a disease or disease state by using protein (#2) and nucleic acid molecule (#3) are distinct from each other because it has different steps, use different products and produce different effects and the protein group (elected) that is examined previously is patentably distinct from method groups as discussed in the previous office action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 30-31 and 32-33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Now, claims 1-2 and 21 will be examined herein.

Applicants' arguments filed on June 26, 2006 have been fully considered but are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Previous rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite with the recitation ""substantially the same amino acid sequence" is withdrawn by virtue of Applicant's amendment of claim 1.

Withdrawn - Claim Rejections - 35 U.S.C. § 112(1)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previous rejection of claim 1-2 and 21 under 35 U.S.C. 112, first paragraph, on Written Description Requirement is withdrawn by virtue of Applicant's amendment of claim 1.

Maintained-Claim Rejections - 35 USC § 112(1)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previous rejection of claims 1-2 and 21 under 35 U.S.C. § 112, first paragraph, as failing to comply with enablement requirement, is maintained and new grounds of rejection is imposed due to recitation "having one N-terminal, C-terminal and/or internal deletion". This rejection has been described in length in previous Office Actions. Applicant's amendments and lengthy arguments have been fully considered but are not deemed persuasive for the following reasons.

As mentioned in the previous office action, Claims 1 and 2 are so broad as to encompass any neuronally active fragments of SEQ ID NO: 1 or any protein having one N-terminal, C-terminal and/or internal deletion of the SEQ ID NO: 1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large

number of proteins broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only several proteins.

Applicants state that in view of amendments of claims 1-2 and 21, the rejection should be withdrawn. This is not found persuasive because the specification only describe active fragment or only protein having one N-terminal, C-terminal and/or internal deletion of the SEQ ID NO: 1, but does not describe the structural boundary as well as functional boundary, which is insufficient to enable the claimed invention without undue experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications including deletions at N-terminal, C-terminal and/or internal of a protein sequence, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable and the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification.

The specification does not support the broad scope of the claims which encompass any or all fragments of SEQ ID NO: 1 or any mutants having N-terminal, C-terminal and/or internal deletions of SEQ ID NO: 1 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting LPP activity; (B) the general tolerance of LPP to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any LPP residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

For all the reasons above, the examiner finds that amendment of claim 1-2 and 21 does not describe the structural features of claimed genus in sufficient detail to overcome the rejection. Therefore, for the reasons above and discussed previously, the rejection is maintained.

Withdrawn-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Previous rejections of Claims 1-2 and 21 under 35 U.S.C. 102(a) as being anticipated by Brauer et al. and Strausberg et al. are withdrawn by virtue of submitting Certified Foreign priority document (02020679.3 of 9/13/2002) translated in English. The document provides support for the claimed invention.

Summary of Pending Issues

The following is a summary of the issues pending in the instant application:

Claims 1-2 and 21 stand rejected under 35 U.S.C. § 112 first paragraph.

Conclusion

Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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